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PTO/SB/33 (07-05)

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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) 1103326-0777 | |
|---|--|---|------------------------------|
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>February 1, 2007</u> Signature <u>John M. Genova</u> Typed or printed name <u>John M. Genova</u> | | Application Number 10/506,345 | Filed Sept 1, 2004 |
| | | First Named Inventor Mikael Dahlstrum | |
| | | Art Unit 1625 | Examiner Morris, Patricia |
| Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. | | | |
| This request is being filed with a notice of appeal. | | | |
| The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. | | | |
| I am the | | Signature <u>John M. Genova</u> | |
| <input type="checkbox"/> applicant/inventor. | | Typed or printed name <u>John M. Genova</u> | |
| <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/86) | | Telephone number <u>212-819-8832</u> | |
| <input checked="" type="checkbox"/> attorney or agent of record. 32,224 Registration number | | Date <u>February 1, 2007</u> | |
| <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 | | | |
| NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below. | | | |
| <input checked="" type="checkbox"/> *Total of <u>2</u> forms are submitted. | | | |

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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1103326-0777**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Mikael Dahlström
Serial No. : 10/506,345
Filing or §371 Date : September 1, 2004
For : ALKYLAMMONIUM SALTS OF
 OMEPRAZOLE AND ESOMPERAZOLE
Examiner : Morris, Patricia L.
Group Art Unit : 1625

| | |
|---|-------------------|
| CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. 1.8 | |
| I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated below at the facsimile number 571-273-8300. | |
| John M. Genova | 32,224 |
| Attorney Name | PTO Reg. No. |
| <i>John M. Genova</i> | 1 February 2007 |
| Signature | Date of Signature |

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PTO/SB/31 and PTO/SB/33)

**REMARKS ACCOMPANYING
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

Applicant requests review of the final rejection in the Office action mailed 2 November 2006 in the referenced application. Attached are Applicant's Pre-Appeal Brief Request for Review (Form PTO/SB/33) and Notice of Appeal (Form PTO/SB/31).

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REMARKS

I. Grounds for requesting pre-appeal brief conference

Applicant requests that an appeal panel of Examiners review the legal and factual basis of the final Office action mailed on 2 November 2006 (the "final Office action") in the referenced application. The final Office action was issued in response to Applicant's communication filed on 28 August 2006.

II. Outstanding rejections

Claims 1-5, 8, 10-12, 15, 17-26 and 28 are under consideration. Claim 27 is withheld from consideration as being drawn to non-elected subject matter.

Claims 1-5, 8, 10, 11, 15, 17-25, 27 and 28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and claim the subject matter which Applicant regards as the invention.

III. Allowable Subject Matter

Claims 12 and 26 are objected to as being dependent on a rejected base claim, but would be allowable if re-written in independent form including all of the limitations of the base and intervening claims.

Claims 1 and 18 would be allowable if re-written or amended to overcome the rejection(s) under 35 U.S.C. §112, second paragraph.

Claims 2-5, 8, 10, 11, 15, 17, 19-25 and 28 would be allowable if re-written to overcome the rejection(s) under 35 U.S.C. §112, second paragraph, and to include all of the limitations of the base and intervening claims.

IV. Error in the Examiner's Rejections

Claims 4, 5, 10 and 21-24 are alleged to lack antecedent basis for the recited limitations. Claims 1-5, 8, 10, 11, 15, 17-25, 27 and 28 are alleged to contain the tradename omeprazole or esomeprazole.

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A. pKa

Dependent claims 4, 5, 21 and 22 recite that the pKa of the compound of independent claim 1 or 18, whichever the case may be, is equal to or greater than about 10 or 10.5. The corresponding disclosure appears at page 4, lines 9-10 of the specification. The Examiner states, however, that claims 1 and 18 fail to clearly claim what is intended by Applicant since the claims do not recite any pKa values.

The claimed invention is directed to a new drug compound, i.e., alkylammonium salts of omeprazole and esomeprazole. An inherent physiochemical characteristic of any drug compound is the pKa value.

According to 37 C.F.R. §75(c), a proper dependent claim refers back to and limits another claim in the same application. Dependent claims 4, 5, 21 and 22 have not been objected to 37 C.F.R. §1.75(c) and, therefore, they are deemed to be proper dependent claims referring back to and limiting another claim in the same application. Specifically, independent claims 1 and 18 are directed to a drug compound and dependent claims 4, 5, 21 and 22 refer back to and further limit the drug compound of claim 1 or 18 by characterizing the claimed compound by a pKa value.

At least to the person of ordinary skill in the art, there is nothing indefinite about the meaning of claims 4, 5, 21 or 22.

B. Crystalline form

Dependent claims 10 and 24 refer back to and further limit the drug compound of claim 1 or 18 by specifying the crystalline form of the compound (See Figures 1 and 2). The corresponding disclosure appears at page 4, lines 15-21, and page 10, line 5, of the specification. This is proper in view of 37 C.F.R. §1.75(c) and unambiguous to the person of ordinary skill in the art.

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C. Species

Dependent claims 8 and 18 refer back to and further limit the drug compound of claim 1 or 18 by specifying a specific species falling within the genus of claim 1 or 18. The corresponding disclosure appears at page 7, lines 10-11 and page 8, lines 1-2, of the specification. As such, claims 8 and 18 are proper dependent claims in view of 37 C.F.R. §1.75(c) and unambiguous to the person of ordinary skill in the art.

D. Omeprazole/Esomeprazole

Claims 1-5, 8, 10, 11, 15, 17-25, 27 and 28 are alleged to contain the tradename omeprazole or esomeprazole. Applicant respectfully submits that the basis for the rejection is incorrect. The tradenames are actually Prilosec® (omeprazole) and Nexium® (esomeprazole magnesium). Omeprazole and esomeprazole are the generic names for the trademark protected name Prilosec® and Nexium, respectively. In support, Applicant submitted a copy of a relevant page from The Merck Index (13th Ed.) as part of the response filed 28 August 2006.

Furthermore, the Office's acceptance of omeprazole and esomeprazole as a proper nomenclature of the claimed compounds is evident by the extensive number of granted patents reciting omeprazole and/or esomeprazole, e.g., US 7,147,869; US 6,926,907; US 6,884,437; US 6,699,885; US 6,569,453; etc. The Examiner should not be permitted to attempt to unilaterally change an established practice which is relied upon by the public.

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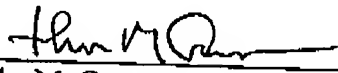
V. Conclusion

The rejection of record under 35 U.S.C. §112, second paragraph, is improper. The rejected dependent claims are proper dependent claims referring back to and limiting independent claim 1 or 18. The features recited by those dependent claims are readily understood by the skilled artisan in view of the specification. The Office has established the practice of accepting the recitation of the generic names, omeprazole and esomeprazole, in the claims. Withdrawal of the §112, second paragraph, is requested.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

Dated: 1 February 2007

Respectfully submitted,



John M. Genova
Reg. No. 32,224

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Enclosures: Pre-Appeal Brief Request for Review (Form PTO/SB/33) (1 page)
Notice of Appeal (Form PTO/SB/31) (1 page)

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